# OUTLIER POLICY

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## Introduction

This document sets out the outlier policy for the Quality and Outcomes in oral and Maxillofacial Surgery (QOMS) Project. It describes how the project will assess the performance of oral and maxillofacial surgery (OMFS) departments participating in the programme and the process to detect and manage potential "outliers", i.e. OMFS departments with indicator values outside the expected range of performance. It is designed to provide transparency about data handling and analysis.

## Background

Clinicians are required to provide accurate, up-to-date information about their clinical practice to ensure patient safety (NHS mandate and General Medical Council's "Good Medical Practice"). Revalidation and the issuing of a licence to practice are predicated on demonstrating acceptable clinical performance. The Medical Director of the NHS has made it clear that the responsibility for maintaining and providing accurate data rests with individual clinicians both in terms of coding of their work and the submission of clinical activity data to national audits where indicated.

With this aim in mind and that of improving quality of care throughout the OMFS specialty, the British Association of Oral and Maxillofacial Surgeons (BAOMS) has initiated the QOMS Project in collaboration with NCEPOD and NFORC-Saving Faces. In this programme, BAOMS is the data controller for QOMS and has responsibility for managing how data are used. The Project Team is responsible for data collection, analysis and publication.

Local OMFS teams are ultimately responsible for data entry with the possible support from their Trust or Health Boards. The collection of data on the eligible procedures is performed through a bespoke online data collection tool. The Project Team will support the local teams with this task by providing quality assurance measures on the data collected, e.g. case ascertainment and coding quality.

As part of the project, the Project Team will regularly assess OMFS departments' performance. The measures have been selected by consulting with the BAOMS membership. Members used their experience as OMFS surgeons supported by evidence derived from the academic literature, NICE publications, and national commissioning targets to guide this selection. The selected measures cover both clinical processes and patient outcomes. Reporting schedules will be regularly communicated to OMFS teams to allow them sufficient time to review their data and ensure it is up to date prior to analysis and reporting.

## Measuring performance, detection and management of "outliers"

Information about choice of indicators will be publically available and included in reports.

## Performance indicators

Performance indicators are intended to provide a valid measure of a health provider's (here an OMFS unit/department within a NHS hospital) quality of care and cover structural, process and outcome aspects of care measures (e.g. timeliness of interventions, length of stay and mortality). The indicators are selected to provide information on service quality for the profession and public.

## Expected performance

Audit activities try to objectively compare the observed vs. expected performance of an OMFS department. The observed performance will be calculated using statistical methods while expected performance are based on either external sources such as research evidence , guidelines (→ Standards) or overall QOMS data (→ Benchmarking). Comparisons are presented using appropriate types of graphs (e.g. control charts, funnel plots).

Audits however should not prevent innovations. Therefore, there may be occasions where expected performance will be determined on the basis of clinical judgement or other external evidence, for example where a hospital's performance is outside of expected performance when assessed against peers, but the performance still meets the relevant standards compatible with safe and effective clinical care.

## Data quality

Any deficiencies in data quality have the potential to distort results and the following data quality will be reported to support clinicians' and public's interpretation of the published results:

- Case ascertainment is the number of records entered into the database compared to the number of eligible cases, derived from external data sources. This will help to inform clinicians, commissioners and the public about the generalisability of the reported outcomes.
- Data completeness refers to the completeness of the data submitted by hospitals for each patient. Complete data is required for accurate analysis and reporting. Without complete data, indicator values for units may be unrepresentative of actual practice.
- Data accuracy will be tested using consistency and range checks, as well as external validation, e.g. against HES. It may involve other methods of validation such as peer review.

OMFS departments should be aware that while QOMS has a duty to report on the data it holds, it is not responsible for the accuracy and completeness of the data submitted. This responsibility rests with the participating OMFS units providing the service to patients. Issues

with clinical audit data (either case ascertainment or data quality) must be addressed by the unit concerned. The role of QOMS is to provide consistent analysis and case mix adjustment of data received from units and to make reports on the process and outcome of care publicly available.

## Risk-adjustment

**Case-mix adjustment:** The comparison of outcomes across healthcare providers must take account of patient characteristics (e.g. patient's age, sex, disease severity and comorbidities) so that differences in outcomes between providers are not due to the differences in the types of patients they treat.

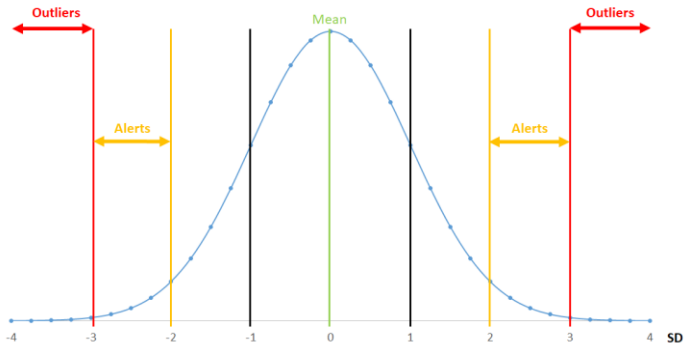
**Unit characteristics / Selection of similar units:** in some cases, the unit / department characteristics should be also considered either by including them in the risk-adjustment model or by limiting the comparisons to units of the same size. In any case, QOMS will report details of the risk-adjustment model characteristics (either published and validated models like P-POSSUM or specifically developed risk-adjustment methods) and their performance.

### Outlier detection

Limits around the expected level of performance are derived using statistical methods and are used to define whether or not a provider is a potential outlier. This process is purely statistical: statistical outliers are not necessarily clinical outliers. For example, if a unit is defined as having performance that is 3 standard deviations (±3 SD) or more below or over expected performance, this means that only 1 in 500 indicator values would be expected to fall outside this threshold if the variation was due to random fluctuations. Identification of a statistical outlier raises questions for clinical judgement, and may require control limits to be refined, for example if performance is very good across the board. Where low numbers are entered for an audit it will not be possible to produce a robust outlier analysis. In summary, a unit will be flagged as (Figure C1):

- A "potential outlier" if the value on an outcome indicator is more than 3 SD from the expected performance level
- An "alert" if the expected level of performance fall between 2 SD and 3 SD. Hospitals that fall between 2 and 3 SD of expected performance will not be contacted as part of the QOMS Outlier process but are encouraged to examine their performance locally and take steps to improve where appropriate.

Figure C1. Statistical definition of potential alerts and alarms/outliers in QOMS.




## Management of potential outliers

The management process of potential outliers for QOMS is summarised in Figure C2. Table C1 provides details of the 7 stages of the process. It involves various people:

- The Project team: the team responsible for managing and running the audit nationally.
- At the unit flagged as a potential outlier, the local clinical lead (...), the provider's clinical governance lead (responsible for clinical governance in the provider NHS trust). The provider Medical Director, and Chief Executive may need to be involved.

The process aims to be feasible and fair to providers identified as potential outliers and sufficiently rapid so as not to unduly delay the publication of comparative information. If after a review of their data, their level of performance is still beyond the 3 SD control limit, the provider will be flagged as an outlier. Finally, consideration will be given to whether it is necessary to suspend the performance of certain index procedures. This will be more likely if poor performance is leading to significant patient harm. It is important to understand that these measures exist for patient safety and that such a suspension will be immediately withdrawn if it can be demonstrated after reviewing the data that performance was outside the "outlier" threshold because of data issues.

There are 2 types of potential outliers (Figure C2):

- Outliers identified as potentially "underperforming" units based on the selected performance metrics. Those units should invest time and resources reviewing their data and providing updated data and other relevant information to the project team. This may include re-audit.
- Positive outliers: departments found to be 3SD or more above expected practice may be contacted for feedback to be shared with other units to help them improve their practice.

## Management of “alerts”

An “alert” indicates that the unit has an indicator value between 2 and 3 SD from the expected level of performance. Providers flagged as “alerts” will not be subject to the review process as outlined in the section above. This is because 1 in 20 providers would be expected to have this size of difference from the national average simply from random variation alone. Nonetheless, to support regular local review of data submissions and clinical practice, QOMS will notify units of their “alert” status. At this stage, the unit should divert sufficient time and resource to reviewing data and submitting more complete data to QOMS, if required. It is recommended that the NHS trust Clinical Governance team is involved at an early stage to provide assistance as required.

## The role of QOMS

As previously stated, QOMS has a duty to report on the data it holds, however, QOMS is not responsible for the accuracy and completeness of the data submitted. This responsibility rests with the teams participating in the audit and issues with data quality must be addressed by the hospital concerned. The project team also aims to support clinical teams in providing high-quality, robust clinical audit data and it is not expected that outliers will be identified frequently. Where potential outliers are identified, the team will provide additional help to hospitals wanting to review data entry and data quality where possible. Hospitals or clinicians with concerns about data quality are urged to contact the project team at the earliest opportunity.

## Identification of Outstanding Performance

A positive outlier is defined as greater than 2 SD above the mean performance on any metric. The project team will contact the team with outstanding performing team(s). Data verification process will involve a site visit with a request for access to clinical records. The approach will be made via the Trust/Health Board Clinical Effectiveness team. The local team will be asked to describe the care process underpinning that performance in detail. This will be the subject of a presentation and award at the BAOMS Annual Scientific Conference and publication on the Clinical Effectiveness page of the BAOMS website.

Approval and review

Approval: <date>, Date of review:  <date>.

Figure C2. Process to address potential issues with OMFS departments - Visual representation

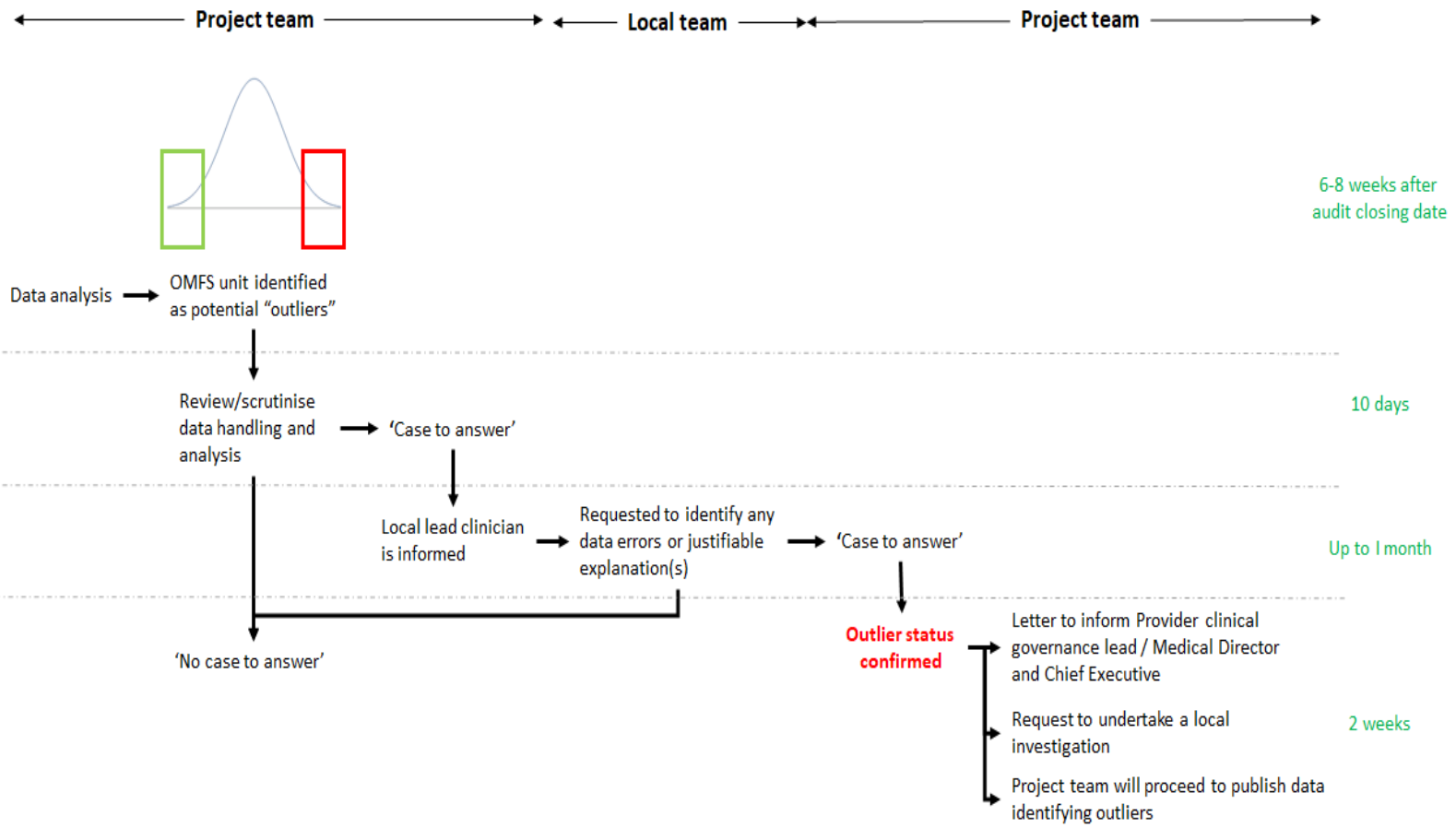

Project team
Local team
Project team
6-8 weeks after audit closing date
Data analysis
OMFS unit identified as potential "outliers"
Review/scrutinise data handling and analysis
'Case to answer'
10 days
Local lead clinician is informed
Requested to identify any data errors or justifiable explanation(s)
'Case to answer'
Up to I month
'No case to answer'
Outlier status confirmed
Letter to inform Provider clinical governance lead / Medical Director and Chief Executive
Request to undertake a local investigation
2 weeks
Project team will proceed to publish data identifying outliers

Table C1. Process to address potential issues with OMFS departments - Table

| Stage | What action? | Who? | Response timeframe |
|---|---|---|---|
| 1 | OMFS units with a performance indicator value beyond the outlier control limit require careful scrutiny of the data submitted and analyses performed. Project team to review/scrutinise data handling and analysis and determine whether there is:<br>→ 'No case to answer':<br>• submitted data in records revised<br>• updated results show provider is not an outlier<br>• details formally recorded.<br>→ 'Case to answer'<br>• data in records revised<br>• re-analysis shows potential outlier status persists | Project team | 10d |
| 2 | The local clinical lead in the unit is informed about the potential outlier status and requested to identify any data errors or justifiable explanation(s). All relevant data and analyses by the project team will be made available to the local clinical lead | Project and local clinical leads | 5d |
| 3 | Local clinical lead to provide written response to QOMS governance team. | Local clinical lead | 25d |
| 4 | Review of local clinical lead's response to determine if these is:<br>→ 'No case to answer'<br>• It is confirmed that the data originally supplied by the provider contained inaccuracies. Re-analysis of accurate data indicates that the level of performance is now within the 3 SD control limits, and the unit is no longer flagged as an outlier.<br>• Data and results will be revised in QOMS records. Details of the provider's response and the review result recorded.<br>• Local Clinical Lead notified in writing.<br>→ 'Case to answer'<br>• It is confirmed that, although the data originally supplied by the provider were inaccurate, analysis of revised data still indicates that the level of performance is still beyond the 3 SD control limits, and the unit is an outlier or<br>• It is confirmed that the originally supplied data were accurate, thus confirming that the provider is an outlier.<br>→ *Proceed to stage 5* | Project team | 30d |
| 5 | Contact local clinical lead by telephone, prior to written confirmation of outlier status; copied to Provider clinical governance lead / Medical Director and Chief Executive. All relevant data and statistical analyses, including previous response from the lead clinician, will be made available to the Provider clinical governance lead / Medical Director and Chief Executive. | Project and Local clinical lead | 5d |
| 6 | Acknowledgement of receipt of the letter. | Provider Chief Executive | 10d |
| 7 | Public disclosure of comparative information that identifies providers (e.g. in annual report). | Project team | |